IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

LUZ LECHUGA,	§	NO. 5:17-CV-728-DAE
	§	
Plaintiff,	§	
	§	
vs.	§	
	§	
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, and BOEHRINGER INGELHEIM INTERNATIONAL GMBH,	§	
	§	
Defendants.	§	
	§	

ORDER GRANTING IN PART AND DENYING IN PART
MOTION TO DISMISS

The matter before the Court is Defendant Boehringer Ingelheim Pharmaceuticals, Inc.'s ("Boehringer" or "Defendant") Motion to Dismiss Plaintiff's Complaint (Dkt. # 11).[1] A hearing was held on this matter on February 8, 2018. At the hearing, Levi Plesset represented Plaintiff Luz Lechuga, and Heidi Levine and Jennifer Foster represented Boehringer.

[1] Plaintiff also named Eli Lilly & Company ("Eli Lilly") as a defendant in this case, but subsequently dismissed her claims against Eli Lilly with prejudice. (See Dkt. # 25.) Eli Lilly had also joined in Boehringer's motion to dismiss, but the Court will moot the motion in regard to Eli Lilly's arguments.

After careful consideration of the memoranda in support of and in opposition to the motion, and arguments of counsel at the hearing, the Court, for the reasons that follow, **GRANTS IN PART** and **DENIES IN PART** the motion to dismiss.

BACKGROUND

Plaintiff's complaint alleges that she is a citizen and resident of El Paso, Texas, and that she suffers from diabetes. (Dkt. # 1 at 2, 6.) According to Plaintiff, on July 24, 2015, she began taking the prescription drug Jardiance in an effort to reduce her blood sugar as treatment for her diabetes. (Id. at 7.) Jardiance is used in the treatment of Type II diabetes, and belongs to a class of drugs called sodium glucose cotransporter 2 ("SGLT2") inhibitors. (See id. at 5.) SGLT2 inhibitors are designed "to inhibit renal glucose absorption with the goal of lowering blood glucose." (Id.) According to the complaint, though Jardiance is indicated only for improved glycemic control in Type II diabetics, Defendants marketed it "for off label purposes, including but not limited to weight loss, reduced blood pressure, and improved glycemic control in type 1 diabetics." (Id.)

According to Plaintiff, sometime after Jardiance's release to the market, the United States Food and Drug Administration ("FDA") received reports that some of its users experienced diabetic ketoacidosis ("DKA"). (Dkt. # 1 at 6.) On July 29, 2015, within days after beginning her Jardiance treatment, Plaintiff

alleges that she suffered DKA resulting in admission to the intensive care unit at Del Sol Medical Center in El Paso, Texas. (Id. at 7.) As a result of the DKA, Plaintiff alleges that she "suffered severe and permanent physical and emotional injuries . . . endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment which will continue in the future." (Id. at 8.)

On August 8, 2017, Plaintiff filed suit against Defendants in this Court.[2] (Dkt. # 1.) Her complaint alleges claims against Defendants, as manufacturers of Jardiance, for: (1) design defect; (2) failure to warn; (3) gross negligence; (4) negligence; (5) breach of express warranty; (6) breach of implied warranty; (7) fraudulent misrepresentation; (8) negligent misrepresentation; (9) negligent design; (10) fraudulent concealment; and (11) fraud. (Id.)

On September 27, 2017, Defendant moved to dismiss the claims against it. (Dkt. # 11.) On November 30, 2017, Plaintiff timely filed a response in opposition to Defendant's motion to dismiss. (Dkt. # 17.) On December 7, 2017, Defendant filed a reply. (Dkt. # 19.)

[2] The other defendants in this case, Boehringer Ingelheim Pharma GmbH & Co. KG and Boehringer Ingelheim International GmbH, have not yet been served.

LEGAL STANDARD

Rule 12(b)(6) allows for dismissal of an action "for failure to state a claim upon which relief can be granted." While a complaint attacked by a Rule 12(b)(6) motion does not need detailed factual allegations in order to avoid dismissal, the plaintiff's factual allegations "must be enough to raise a right to relief above the speculative level." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007); see also Cuvillier v. Taylor, 503 F.3d 397, 401 (5th Cir. 2007). A plaintiff's obligation "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. The Supreme Court recently expounded on the Twombly standard, explaining that a complaint must contain sufficient factual matter to state a claim to relief that is plausible on its face. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. In evaluating a motion to dismiss, the Court must construe the complaint liberally and accept all of the plaintiff's factual allegations in the complaint as true. See In re Katrina Canal Breaches Litigation, 495 F.3d 191, 205 (5th Cir. 2009).

ANALYSIS

Defendant's motion to dismiss argues that (1) all of Plaintiff's claims are time-barred by the applicable statute of limitations; (2) section 82.007 of the

Texas Civil Practice and Remedies Code requires dismissal of Plaintiff's failure to warn claims; (3) Plaintiff's complaint does not plausibly allege any cause of action; and (4) Plaintiff's strict liability design defect and negligent representation claims fail because they are not recognized under Texas law. (Dkt. # 11.)

A. Statute of Limitations

Defendant first contends that Plaintiff's claims—which all arise out of her personal injuries as a result of taking Jardiance—are barred by Texas' two-year statute of limitations on such claims. (Dkt. # 11 at 4.) Plaintiff's complaint alleges that she developed DKA on or about July 29, 2015, but the record in this case reflects that she did not commence this lawsuit until August 2, 2017, more than two years after her alleged injuries occurred. (See Dkt. # 1.) Thus, according to Defendant, Plaintiff's claims should be dismissed on this basis and because she failed to plead that the Texas discovery rule applies.

The parties do not contest the application of Texas substantive law to this matter. In Texas, a two-year statute of limitations governs personal injury actions. See Tex. Civ. Prac. & Rem. Code Ann. § 16.003(a) (West 2005). "A personal injury action must be filed within two years from the date the cause of action accrues." Porterfield v. Ethicon, Inc., 183 F.3d 464, 467 (5th Cir. 1999). "A cause of action accrues when the legal wrong is completed and the plaintiff is entitled to commence suit, even if the party is unaware of the wrong." Id.

"Texas courts have adopted a discovery rule that tolls the statute of limitations until the plaintiff discovers, or through the exercise of reasonable care and diligence should have discovered, the nature of the injury." Id. Discovery does not necessarily mean "actual knowledge of the particulars of a cause of action." Vaught v. Showa Denko K.K., 107 F.3d 1137, 1140 (5th Cir. 1997). Instead, the question is whether the plaintiff has "knowledge of facts which would cause a reasonable person to diligently make inquiry to determine his or her legal rights." Id. at 1141–42.

Plaintiff, in response, contends that at the time she suffered DKA, "she would have no way of attributing her renal failure to the ingestion of defendants' product-let alone that they acted wrongfully or negligently in its manufacturing." (Dkt. # 18 at 6.) For this reason, Plaintiff asks the Court to apply the discovery rule and find that her claims are not time-barred. (Id.)

First, the Court finds that Plaintiff's failure to plead the discovery rule in her pleadings is not fatal to her claims because the Court, as discussed below, will allow Plaintiff the opportunity to amend her complaint within twenty-one days of the date of this Order. Should Plaintiff choose to rely on the discovery rule, she must allege it in her complaint. Nevertheless, even if Plaintiff had alleged it in the operative complaint before the Court at the present time, the Court would not dismiss Plaintiff's claims on the basis that the discovery rule is inapplicable at this

stage of the proceedings. Though not cited by either party, and neither party discussed it at the hearing on the motion, the Court notes that the Eleventh Circuit Court of Appeals recently noted federal courts' inconsistency in interpreting the Texas discovery rule to products liability cases such as the one here.[3] See Bergin v. Mentor Worldwide LLC, 871 F.3d 1191, 1194 (11th Cir. 2017). In noting the inconsistency in the Fifth Circuit, the Eleventh Circuit stated

> As to the Fifth Circuit, which is the federal circuit in which Texas is located, that court has likewise issued inconsistent rulings. In Timberlake v. A.H. Robins Co., 727 F.2d 1363 (5th Cir. 1984), the plaintiff sued the manufacturer of a Dalkon Shield intrauterine device (IUD) that allegedly caused her injury, having developed symptoms in 1978, but not suing until 1981 when she saw a television program suggesting that the manufacturer may have been negligent in its manufacture and sale of the product. Concluding that the plaintiff had failed to sue within the applicable Texas statute of limitations, the court rejected her argument that "the statutory period should be tolled until the plaintiff learns that the defendant's conduct may have been wrongful," holding that the discovery rule did not apply and that the statute of limitations began in 1978 when the plaintiff "knew of her injury and its cause." Id. at 1365, 1366. Stated more formally, in response to plaintiff's argument "that Texas law applies a three-pronged analysis with regard to the discovery rule, and that all three elements—injury, causation in fact, and legal injury—must coalesce before the statute of limitations begins to run," the court was "not persuaded that this is an accurate statement of the applicable law." Id. at 1365.
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> Nevertheless, in that same year, the Fifth Circuit issued two other opinions that reached a different result on similar facts. In Woodruff v. A.H. Robins Co., 742 F.2d 228 (5th Cir. 1984), the plaintiff developed a severe pelvic infection following the insertion of

[3] The Eleventh Circuit issued the opinion on September 20, 2017, seven days before Defendant's motion to dismiss was filed in this case.

> an IUD, after which the IUD was removed in 1973 and the plaintiff underwent a hysterectomy. She, however, did not file suit until 1981 when she read a newspaper article suggesting a possible causal connection between the Dalkon Shield and her injuries. The Fifth Circuit rejected the defendant's argument that her lawsuit was time-barred, relying on Mann v. A.H. Robins Co., 741 F.2d 79, 81 (5th Cir. 1984), which held that a claim does not accrue under the Texas discovery rule until a plaintiff learns of her injury's negligent cause. The court in Woodruff concluded that the plaintiff's claim had not accrued until a newspaper article alerted her to the possible connection between the Dalkon Shield and her physical injuries.

Bergin, 871 F.3d at 1194–95. The Eleventh Circuit went on to review Texas cases and further noted the inconsistent application of the Texas discovery rule. See id. The Eleventh Circuit ultimately certified the following question to the Texas Supreme Court: "In a product liability case, does Texas' discovery rule require a plaintiff to have some knowledge of possible wrongdoing on the part of the manufacturer—i.e., a causal connection between the injury and the manufacturer's conduct—before the plaintiff's claims can accrue?" Id. at 1197. Unfortunately for the Court in the instant case, however, the question was ultimately decertified when the appeal was voluntary dismissed by the parties, thus decertifying the question to the Texas Supreme Court. Id. (see history of case).

While it is true, as Defendant points out to the Court, that the Eleventh Circuit and the majority of the cases discussed therein considered the Texas discovery rule in relation to implanted devices—as opposed to prescription medication—the Court will not slice the issue so thin, and Defendant cites to no

other court that has done so. Furthermore, the Eleventh Circuit did not qualify such a narrow question to the Texas Supreme Court. See Bergin, 871 F.3d at 1197. Thus, given the uncertainty in application of the Texas discovery rule to the facts in the present products liability case, the Court will not deny Defendant's motion to dismiss on the basis that Plaintiff's claims are time-barred.[4]

B. Section 82.007 of the Texas Civil Practice and Remedies Code

Defendant next contends that Plaintiff's failure to warn claims must be dismissed because section 82.007 of the Texas Civil Practice and Remedies Code allows for the presumption that Jardiance's FDA-approved warning label is adequate. (Dkt. # 11 at 6.) Because the FDA approved Jardiance's warning label and because Plaintiff has not plausibly pled any of the enumerated exceptions to section 82.007, Defendant asserts that Plaintiff's failure to warn claims must be dismissed. (Id.)

Under Texas law, all causes of action based on a claim of inadequate warnings or information, regardless of how they are characterized, are grouped together as inadequate warning cases and are governed by section 82.007 of the

[4] The Court also notes the Fifth Circuit's "review of Texas and Fifth Circuit cases applying the discovery rule to [implant injuries in products liability cases] indicates that dismissal typically occurs at the summary judgment phase, after facts added to the record can lead to more fully formed conclusions." Brandau v. Howmedica Osteonics Corp., 439 F. App'x 317, 322 (5th Cir. Aug. 23, 2011) (citing Porterfield, 183 F.3d at 466; Vaught, 107 F.3d at 1147; Woodruff, 742 F.2d at 230; Mann, 741 F.2d at 82).

Texas Civil Practice and Remedies Code. Del Valle v. Qualitest Pharms., Inc., No. B–11–113, 2012 WL 2899406, *2 (S.D. Tex. June 22, 2012), appeal dismissed in part, No. 12–41148, 2012 WL 4747259 (5th Cir. Feb. 5, 2012). Under section 82.007, an FDA approval creates a rebuttable presumption that the approved warning is adequate. Tex. Civ. Prac. & Rem. Code Ann. § 82.007(a). Section 82.007(a) provides,

> In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant . . . manufacturer . . . [is] not liable . . . if (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration. . . .

Id. The statute further provides five enumerated means of rebutting this presumption. See id. § 82.007(b). One such rebuttal is that:

> (1) the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury . . . .

Id. § 82.007(b)(1).

Plaintiff contends that her complaint clearly indicates that the exception in section 82.007(b)(1) applies in this case. (Dkt. # 18 at 6.) Plaintiff asserts that her complaint explicitly states that "[t]he defendants had knowledge of, and were in possession of evidence demonstrating that JARDIANCE caused

serious side effects" but that "[n]otwithstanding their knowledge, the Defendants continued to market JARDIANCE by providing false and misleading information with regard to JARDIANCE's safety to regulatory agencies, the medical community, and consumers of JARDIANCE." (Dkt. # 1 at 19.) The complaint further alleges that "Defendants made fraudulent misrepresentations with respect to JARDIANCE in the following particulars: a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that JARDIANCE had been tested and found to be safe and effective for the treatment of diabetes . . ." (Id. at 31.) Additionally, the complaint states that "Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submission that JARDIANCE was safe and fraudulently withheld and concealed information about the severity of the substantial risks of using JARDIANCE . . ." (Id. at 39.)

Defendant contends, however, that Plaintiff's allegations in her complaint are insufficient to meet her pleading burden because her "fraud-on-the-FDA allegations sound in fraud and must be pled with particularity under Rule 9(b)" of the Federal Rules of Civil Procedure. (Dkt. # 19 at 4.) According to Defendant, Plaintiff's complaint lacks particular facts regarding the alleged misrepresentations to the FDA and should be dismissed. (Id.) Defendant further

contends that Plaintiff's complaint does not allege that the FDA itself has ever determined that Defendant committed fraud, and thus, all of her claims challenging the adequacy of Jardiance's warnings must be dismissed. (Id. at 5.)

In Lofton v. McNeil Consumer & Specialty Pharmaceuticals, 672 F.3d 372, 374 (5th Cir. 2012), the Fifth Circuit held that unless the FDA itself finds fraud, federal law preempts section 82.007(b)(1) and thus requires parties in failure-to-warn cases to allege that the manufacturer withheld or misrepresented material information to the FDA in order to rebut the presumption that the drug manufacturer was not liable. "[W]here the FDA has not found fraud, the threat of imposing state liability on [a] drug manufacturer for defrauding the FDA intrudes on the competency of the FDA and its relationship with regulated entities." Id. at 380. The FDA is responsible for policing fraud and "has the authority to investigate fraud, 21 U.S.C. § 372, consider citizen petitions, 21 C.F.R. § 10.30, and seek criminal and civil penalties particular to fraud-on-the-FDA, 21 U.S.C. § 332–32." 672 F.3d at 376 n.2. Furthermore, section 82.007(b)(1)'s term "required information" refers to federal requirements under the [Federal Drug and Cosmetic Act ("FDCA")] and what is "material" and "relevant" must be decided by the FDA, not state court juries. Id. at 379. Thus, the Fifth Circuit determined

that the state law claim would conflict with the FDA's authority to punish fraud on the agency, so it was preempted by the FDCA.[5] Id. at 376.

Accordingly, Lofton stands for the proposition that if a plaintiff in a failure to warn case fails to allege that the FDA found fraud on the part of a manufacturer, she cannot rebut the § 82.007 presumption of non-liability, and thus the plaintiff's failure to warn claim must be dismissed. See Lofton, 672 F.3d at 380. Here, Plaintiff has not alleged that the FDA has found fraud, and thus her fraud-on-the-FDA claims are preempted and cannot be used to rebut section 82.007's presumption of non-liability for her failure to warn, nor has she identified any other exception that might apply to her case. See id. At this time, the Court will dismiss this claim without prejudice. Plaintiff, however, will be granted leave to file an amended complaint within twenty-one days that meets the requirements of that statute and Rule 12(b)(6).

C. Design Defect Claims

Defendant next moves to dismiss Plaintiff's design defect claims, counts I (strict liability) and IX (negligent design), on the basis that Plaintiff has not plausibly pled how Jardiance is defective in support of such claims. (Dkt. # 11 at 12.) Defendant also contends that Plaintiff's complaint fails to allege a safer

[5] The Fifth Circuit recognized there is a split in the Circuits addressing similar provisions in other states. Id. at 377. This Court is bound by the Fifth Circuit's ruling in Lofton.

alternative design as required to state a design defect claim under Texas law. (Id. at 13.)

"The duty to design a safe product is 'an obligation imposed by law.'" Am. Tobacco Co., Inc. v. Grinnell, 951 S.W.2d 420, 432 (Tex. 1997) (quoting McKisson v. Sales Affiliates, Inc., 416 S.W.2d 787, 789 (Tex. 1967)); accord Robins v. Kroger Co., 982 S.W.2d 156, 161 (Tex. App.—Houston [1st Dist.] 1998, pet. denied). "A design defect renders a product unreasonably dangerous as designed, taking into consideration the utility of the product and the risk involved in its use." Brockert v. Wyeth Pharms., Inc., 287 S.W.3d 760, 769 (Tex. App.—Houston [14th Dist.] 2009, no pet.) (citing Gen. Motors Corp. v. Sanchez, 997 S.W.2d 584, 588 (Tex. 1999)).

To recover on a design defect claim in Texas, a plaintiff must show: (1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was the producing cause of the injury for which the plaintiff seeks recovery. Timpte Indus., Inc. v. Gish, 286 S.W.3d 306, 311 (Tex. 2009) (citing Texas Civ. Prac. & Rem. Code § 82.005); Hernandez v. Tokai Corp., 2 S.W.3d 251, 255–56 (Tex. 1999)).

For her design defect claims, Plaintiff alleges in her complaint that Jardiance was designed "in an unsafe, defective, and inherently dangerous condition" and "contained unreasonably dangerous design defects," including that

Jardiance is "designed to inhibit renal glucose reabsorption," but that as a result of the design, "excess glucose is not metabolized, but instead is excreted through the kidneys of a population of consumers already at risk for kidney disease." (Dkt. # 1 at 5, 9, 36.) Plaintiff's complaint also alleges that since Jardiance's release, "the FDA has received a significant number of reports of [DKA] among users of Jardiance." (Id. at 6.) Plaintiff also alleges that Jardiance was unreasonably dangerous in its design and that "its foreseeable risks exceeded the alleged benefits associated with Jardiance's design or formulation," and that its design "posed a greater likelihood of injury than other diabetic drugs and was more dangerous than an ordinary consumer could reasonably foresee or anticipate." (Id. at 10.)

Plaintiff's complaint further alleges that there are other alternative drug designs with safer profiles than Jardiance. (Dkt. # 1 at 12, 37.) Plaintiff alleges that other diabetes drugs have lower risks than Jardiance and that Defendant could have designed Jardiance to make it less dangerous. (Id. at 10, 11.) Additionally, Plaintiff asserts that when Defendant designed Jardiance, "the state of the industry's scientific knowledge was such that a less risky design was attainable." The complaint also alleges that due to the defective design of Jardiance, Plaintiff was injured when she suffered DKA "resulting in admission to the intensive care unit at Del Sol Medical Center in El Paso after only five days of taking Jardiance." (Id. at 7, 12, 37.)

In support of dismissal of these claims, Defendant contends that Plaintiff's complaint simply recites the elements of a design defect claim, but does not contain detailed factual allegations to support the elements. (Dkt. # 11 at 13.) Additionally, Defendant asserts that Plaintiff's complaint fails to allege a safer *design*, only that a safer *product* was available. (Id. at 13–14.) Defendant argues that Plaintiff cannot demonstrate the existence of a safer alternative design by pointing to a substantially different product in support of the claim. (Id. at 14.)

A plaintiff cannot demonstrate the existence of a "safer alternative design" "by pointing to a substantially different product, even when the other product has the same general purpose as the allegedly defective product." Brockert v. Wyeth Pharmaceuticals, Inc., 287 S.W.3d 760, 770 (Tex. App.—Houston [14 Dist.] 2009, no pet.) (citing Theriot v. Danek Med., Inc., 168 F.3d 253 (5th Cir. 1999)). "[A] safer alternative design must be one for the product at issue," not a different product. Id.

Plaintiff has adequately alleged, or raised reasonable inferences of, respects in which Jardiance is plausibly defective so as to survive dismissal at this stage. Rule 8 does not require that Plaintiff come to court with specific design specifications or accounts of the mechanisms of Jardiance's action. Additionally, at this stage of the proceedings, the Court finds that Plaintiff has sufficiently alleged a safer alternative design to withstand dismissal as the Court has no way to

determine without further evidence whether the other diabetic drugs that Plaintiff alleges are more safely designed have substantially different components than Jardiance so as to make them completely different products. Instead, this is a more proper determination at the summary judgment stage. Once put to their proof, Plaintiff will be required to show the existence of an alternative design for Jardiance, not merely alternative therapies or wholly different products. See Theriot, 168 F.3d at 255. The question before the Court is not whether Plaintiff has alleged a prima facie case, but whether she has "'raised a reasonable expectation that discovery will reveal evidence'" to support liability for the alleged wrongdoing. Adams v. City of Indianapolis, 742 F.3d 720, 724 (7th Cir. 2014) (quoting Twombly, 550 U.S. at 556).

While the Court notes that Plaintiff's allegations would be stronger and clearer if she included a personalized causal connection between the above-recited allegations and own her DKA—for example, that she was particularly vulnerable to ketone increases—the deficiency is not fatal to her complaint. The core of Plaintiff's allegations regarding her design defect claims are that Jardiance carries with it a higher risk of DKA—which Plaintiff alleges to have experienced—as compared to other SGLT2 inhibitors or other kinds of glucose-lowering medication. Accordingly, the Court finds that Plaintiff's complaint plausibly states design defect claims for counts I and IX.

D. Negligence Claims

Defendant moves to dismiss Plaintiff's negligence claims in counts III and IV of her complaint on the basis that she has not plausibly pled such claims. (Dkt. # 11 at 14.) Defendant argues that to the extent the negligence claim is premised on (1) a failure to warn, the claims fail because of section 82.007's presumption of adequacy, as discussed above; (2) a design defect or manufacturing defect, she has improperly plead the claim; and (3) an alleged failure to test, Plaintiff offers no facts to support such a claim. (Id. at 14–16.) Additionally, Defendant contends that Plaintiff's gross negligence claim should be dismissed for the same reasons. (Id. at 16.)

Under long-established Texas law, the elements of a negligence claim are: (a) a legal duty; (b) breach of that duty; and (c) damages proximately caused by the breach. E.g., Nabors Drilling, U.S.A., Inc. v. Escoto, 288 S.W.3d 401, 404 (Tex. 2009); Lane v. Halliburton, 529 F.3d 548, 565 (5th Cir. 2008). Additionally, under Texas law, "gross negligence" is a heightened form of "negligence" that requires proof (in addition to the ordinary elements of negligence) of: (1) an act or omission that, viewed objectively from the actor's standpoint, involved "an extreme degree of risk"; and (2) the actor had actual, subjective awareness of the risk and proceeded, nevertheless, with a "conscious indifference." Lane, 529 F.3d

at 565; Guzman v. Inter Nat'l Bank, No. 13–07–00008–CV, 2008 WL 739828, at *3–4 (Tex.App.—Corpus Christi Mar. 20, 2008, no pet.).

First, to the extent Plaintiff's negligence claims are premised on a failure to warn theory, the Court has already found, as discussed above, that Plaintiff has not alleged that the FDA has found fraud in order to support such a theory. Plaintiff may amend her complaint, should she choose to do so, within twenty-one days. To the extent the negligence claim is premised on a design defect theory or failure to test, the Court finds that Plaintiff has properly pled such claims to survive dismissal at the 12(b)(6) stage. Plaintiff's complaint alleges that Defendant has a duty to "properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and otherwise ensure that Jardiance was not unreasonably dangerous for its intended purpose." (Dkt. # 1 at 11.) Plaintiff also alleges that Defendant had a duty to "disclose to health care professionals the causal relationship or association of Jardiance to the development of Plaintiff's injuries." (Id. at 21.) As alleged by Plaintiff, this duty was breached by Defendant by, among others, (1) failing to exercise reasonable care in the design; (2) failing to properly test Jardiance; (3) failing to conduct sufficient post-marketing testing and surveillance of Jardiance; and (4) failing to exercise due care in the advertising and promoting

Jardiance. (Id. at 23–24.) Plaintiff alleges that as a result of the breach of Defendant's duty, she suffered DKA. (Id. at 7.)

Likewise, the Court finds that Plaintiff has sufficiently pled the elements and facts necessary to sustain a gross negligence claim at this stage of the proceedings. Accordingly, to the extent her negligence claims are not premised on a failure to warn theory, the Court finds that Plaintiff's complaint plausibly states negligence claims for counts III and IV.

E. Breach of Warranty Claims

Defendant also moves to dismiss Plaintiff's breach of warranty claims, counts V and VI, on the basis that they are either subject to section 82.007, discussed above, or that she has not properly pled them. (Dkt. # 11 at 17.) Specifically, to the extent the claims are not based on a failure to warn theory, Defendant contends that (1) Plaintiff failed to provide the requisite pre-suit notice, and (2) she has not identified an express warranty upon which she can base her claims. (Id.)

To recover on a breach of warranty claim in Texas, "the buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." Tex. Bus. & Com. Code Ann. § 2.607(c)(1). The burden of "alleging and proving proper notice" is on the buyer, and "[f]ailure to notify the seller of the breach, thereby allowing the seller

an opportunity to cure, bars recovery on the basis of breach of warranty." Lochinvar Corp. v. Meyers, 930 S.W.2d 182, 189 (Tex. App.—Dallas 1996, no writ). "It is not essential under [§ 2.607] that the buyer's notification of defective product specifically set forth in detail every objection the buyer has to the fitness of the product; it is only necessary that the seller be informed that there is a claimed breach of the warranty of fitness." Melody Home Mfg. Co. v. Morrison, 502 S.W.2d 196, 203 (Tex.App.—Houston [1st Dist.] 1973, writ ref'd n.r.e.).

To the extent either of Plaintiff's breach of warranty claims are premised on a failure to warn, they are subject to the same fate as the other failure to warn claims, discussed above, and Plaintiff may amend her complaint to re-plead such claims. To the extent that the breach of warranty claims are not premised on a failure to warn theory, Defendant contends that Plaintiff has not pled that she notified Defendant "within a reasonable time" of any alleged breach, thus barring her claims. (Dkt. # 11 at 17.)

The Court agrees with Defendant's contention. Plaintiff has not pled in her complaint that she complied with the pre-suit notice requirements. Instead, Plaintiff contends only generally that a justifiable delay may except the pre-suit notice requirement, but she does not provide any clear authority in support. (Dkt. # 18 at 12–13.) Plaintiff also asserts that Defendant has not been prejudiced by her failure to notify. (Id.) Despite Plaintiff's assertions, the Court must still dismiss

her breach of warranty claims without prejudice. She may, however, amend her complaint to properly allege that she complied with section 2.607(c)(1)'s pre-suit notice requirements within twenty-one days.

F. Fraud, Misrepresentation, and Consumer Protection Claims

Defendant next moves to dismiss Plaintiff's claims for fraudulent misrepresentation, negligent misrepresentation, and fraud (counts VII, VIII, X, XI), on the basis that they are in fact failure to warn claims and should be dismissed pursuant section 82.007, as discussed above. (Dkt. # 11 at 18.) Defendant also contends that Plaintiff has not plausibly pled these claims with particularity. (Id.)

Again, to the extent her fraud and misrepresentation claims are premised on a failure to warn theory, they will be dismissed without prejudice. Plaintiff may amend her complaint to properly allege such a theory within twenty-one days. To the extent the claims are not premised on this theory, the Court must apply Rule 9(b)'s heightened pleading standard to Plaintiff's fraud and negligent misrepresentation claims, which requires that the claims be alleged "with particularity." United States ex rel. Steury v. Cardinal Health, Inc., 625 F.3d 262, 266 (5th Cir. 2010) (internal quotation marks and citations omitted). Plaintiff does not dispute that Rule 9(b)'s heightened pleading standard applies to these claims. (See Dkt. # 18 at 13.)

The elements of a fraud claim are that the defendant (1) made a material representation that was false; (2) knew the representation was false or made it recklessly as a positive assertion without any knowledge of its truth; (3) intended to induce plaintiff to act upon the representation; and (4) the plaintiff actually and justifiably relied upon the representation and thereby suffered injury. Ernst & Young, L.L.P. v. Pac. Mut. Life Ins. Co., 51 S.W.3d 573, 577 (Tex. 2001). Fifth Circuit "precedent interprets Rule 9(b) strictly, requiring the plaintiff to specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent." Flaherty & Crumrine Preferred Income Fund, Inc. v. TXU Corp., 565 F.3d 200, 207 (5th Cir. 2009).

In Texas, the four elements to establish a negligent misrepresentation claim include: "(1) [a] representation is made by a defendant in the course of his business, or in a transaction in which he has a pecuniary interest; (2) the defendant supplies "false information" for the guidance of others in their business; (3) the defendant did not exercise reasonable care or competence in obtaining or communicating the information; and (4) the plaintiff suffers pecuniary loss by justifiably relying on the representation." Gen. Elec. Capital Corp. v. Posey, 415 F.3d 391, 395–96 (5th Cir. 2005) (internal quotations omitted).

Defendant contends that Plaintiff has failed to allege any details concerning the time, place, and content of any alleged misrepresentation, concealment, or other fraudulent acts by Defendant. (Dkt. # 11 at 18.) Defendant further asserts that while Plaintiff has named several defendants, she has failed to distinguish between either of them, only that they collectively misrepresented Jardiance was safe. For these reasons, Defendant contends that Plaintiff's fraud and negligent misrepresentation claims should be dismissed.

In response, Plaintiff asserts that the same allegations can support a fraud claim against the Defendants as a collective. (Dkt. # 18 at 14.) She argues that because each of the Defendants "engaged in the process of designing, manufacturing, labeling, and promoting Jardiance, it should come as no surprise that Plaintiff has alleged identical claims against each defendant." (Id.) Plaintiff also contends that she has adequately pled the "who, what, when, where and how" as to all Defendants for her fraud and negligent misrepresentation claims. (Id.) In support, Plaintiff asserts that her complaint alleges the (1) "who" when she pleads the Defendants as a collective (see Dkt. # 1 at 2–3); (2) "what" when she pleads that Defendants are responsible for Jardiance (id. at 4); (3) "how" and "when" in that she pleads the fraud occurred through marketing and promotional materials provided to the medical community and consumers (id. at 19), labeling information, detail persons, seminar presentations, and regulatory materials (id. at

31), and through Defendants' sale representatives—their agents (id. at 34); and (4) "when" was also pled when Jardiance was approved by the FDA in August 2014, and when she suffered DKA in July 2015 (id. at 5, 7).

The Court finds that Plaintiff has not met the heightened pleading standard of Rule 9(b) for her fraud and negligent misrepresentation claims. Plaintiff has failed to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Plaintiff's complaint only generally alleges that each defendant made a fraudulent statement, but does not identify a specific employee or other speaker from each Defendant who made a false material representation. "Were this claim being analyzed under a lesser standard that did not require specifying, the who, what, when, where and how, the court might reach a different conclusion." Schouest v. Medtronic, Inc., 92 F. Supp.3d 606 (S.D. Tex. 2015). Thus, under a strict Rule 9(b) analysis, Plaintiff has not sufficiently pled her fraud and negligent misrepresentation claims. At this time, the Court will dismiss these actions without prejudice. Plaintiff will be given an opportunity to amend her complaint to address these deficiencies.

G. Section 402A of the Restatement (Second) of Torts, comment K

Defendant also moves to dismiss Plaintiff's strict liability design defect claim on the basis that, in Texas, the Restatement (Second) of Torts, section 402A, comment K, effectively exempts FDA-approved prescription drugs from

strict liability claims for design defect. (Dkt. # 11 at 19.) Likewise, Defendant contends that Plaintiff's negligent misrepresentation claim must be dismissed because Texas does not recognize a tort for negligent misrepresentation leading to physical harm, as opposed to pecuniary loss. (Id. at 20.) Instead, Defendant asserts that such a claim is only available when false information is supplied to a plaintiff for guidance of others in a business. (Id.) Because Plaintiff has not alleged that she purchased Jardiance for business purposes, Defendant contends that her negligent misrepresentation claim should be dismissed on this basis also.

In Texas, prescription drug design defect claims are governed by comment k to Section 402A of the Restatement (Second) of Torts. See Brockert v. Wyeth Pharmaceuticals, Inc., 287 S.W.3d 760, 769 (Tex.App.—Houston [14 Dist.] 2009); Keene Corp. v. Yeager, 1994 WL 34159, *5 (Tex.App.—Dallas 1994, writ denied). Comment k "recognizes that '[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use,' and that some drugs 'for this very reason cannot legally be sold except to physicians, or under the prescription of a physician.'" Under [comment k], a prescription drug is unreasonably dangerous in design if it is not 'accompanied by proper directions and warning.'" Gerber v. Hoffmann–La Roche Inc., 392 F.Supp.2d 907, 922 (S.D. Tex. 2005) (quoting Uniroyal Goodrich Tire Co. v. Martinez, 977 S.W.2d 328, 335 (Tex. 1998)). Courts have interpreted

this provision as foreclosing design defect claims pertaining to prescription drugs where the products were accompanied by proper directions and warnings. See Hackett v. G.D. Searle & Co., 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002) ("The Court thus holds that under Texas law and comment k of the Restatement, Defendant can only be held strictly liable if the drug was not . . . accompanied by proper warnings."); Holland v. Hoffman-La Roche, Inc., No. 3:06-CV-1298-BD, 2007 WL 4042757, at *3 (N.D. Tex. Nov. 15, 2007) (same); cf. Reyes v. Wyeth Labs., 498 F.2d 1264, 1274 (5th Cir. 1974) ("[A]n unavoidably unsafe product is neither defective nor unreasonably dangerous if . . . accompanied by proper directions and warning").

Some district courts in this Circuit have characterized comment k as an affirmative defense only to a strict liability design defect claim. See, e.g., Romero v. Wyeth Pharms., Inc., 2012 WL 12547449, at *6 (E.D. Tex. Aug. 31, 2012) (citing Scelta v. Boehringer Ingelheim Pharms., Inc., 404 F. App'x 92, 95 (8th Cir. 2010) ("Comment k provides for an affirmative defense to the design defect cause of action described in section 402A of the Restatement (Second) of Torts."); Moss v. Wyeth, Inc. 872 F. Supp. 2d 162, 169 (D. Conn. 2012) (in the context of HRT litigation, recognizing the majority view that comment k is an affirmative defense). As an affirmative defense, it would be Defendant's burden to "show that the drug's risk is unavoidable by demonstrating that, given the current

state of knowledge, no feasible alternative design exists that would accomplish the same purpose with a lesser risk. Next, the manufacturer must demonstrate that the drug's overall benefits outweigh the risks it presents to individual safety." Hanrahan v. Wyeth, Inc., No. 4:04-CV-01255, 2012 WL 2395881, at *13 (E.D. Mo. June 25, 2012) (quotations and citations omitted) (HRT litigation). Here, Defendant has offered no evidence, at this stage of the proceedings, that Jardiance is an unavoidably unsafe product so as to avail them of comment k's protection. See DaimlerChrysler Motors Co., LLC v. Manuel, 362 S.W.3d 160, 187 n.27 (Tex. App.—Fort Worth 2012, no pet.) (recognizing that burden of proof is on party asserting affirmative defense); Hanrahan, 2012 WL 2395881, at *13 (holding Wyeth could not avail itself of comment k protection where it failed to meet its burden of production). The Court will not dismiss Plaintiff's design defect strict liability claim on this basis.

As for Plaintiff's negligent misrepresentation claim, the Court has already determined that Plaintiff has not met the pleadings requirements under Rule 9(b) for that claim; thus, the Court will not consider Defendant's alternative argument regarding this claim.

CONCLUSION

Based on the foregoing, the Court **GRANTS IN PART** and **DENIES IN PART** Defendant's Motion to Dismiss Plaintiff's Complaint (Dkt. # 11). The motion is **GRANTED** as to Plaintiff's claims based on a failure to warn theory, breach of warranty, fraud, and negligent misrepresentation and these claims will be **DISMISSED WITHOUT PREJUDICE**. Plaintiff may amend her complaint to re-plead these claims within twenty-one days of the date of this Order. Defendant's motion to dismiss is **DENIED** as to Plaintiff's claims based on design defect and negligence.

IT IS SO ORDERED.

DATED: San Antonio, Texas, February 9, 2018.

David Alan Ezra
Senior United States Distict Judge